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13. ABSTRACT *(Maximum 200*

With eye injuries constituting a significant percentage of all combat casualties, proper, definitive ophthalmological care in the far forward field medical system is needed. Our goal is to develop a non-mydriatic ophthalmoscope/fundus camera suitable for use under field conditions that will permit acquisition and storage of digital images and rapid assessment of basic visual function.

We surveyed the existing ophthalmoscope/fundus camera technologies to establish an awareness of the state-of-the-art in this field. Based on the survey results, we consider scanning laser ophthalmoscopy the most suitable technology for the proposed system. The nature and frequency of combat related eye injuries was investigated to determine the desired capabilities of a baseline scanning laser system. The performance envelope of the baseline system was specified based on the military standards for equipment design and environmental requirements. A feasibility/design trade-off study was conducted based on the desired capabilities and performance envelope. Software was developed to acquire and store non-mydriatic, digital fundus images with our COTS scanning laser ophthalmoscope and to transmit these over the Internet. Proof-of-concept hardware for implementing basic visual function testing into the COTS scanning laser ophthalmoscope was developed and successfully tested.

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1. Introduction

Eye injuries constitute approximately 10% of combat casualties. Currently, proper, definitive ophthalmologic care is not routinely available to eye-injured soldiers far forward in the field medical system. The operational and environmental limitations of existing ophthalmoscopes and fundus cameras preclude their use under field conditions, where diagnostic instrumentation must be portable and able to survive wide variations in meteorological conditions. Furthermore, the care provider on the scene at a forward medical treatment facility may not be able to provide the specialty care required for a unique injury without assistance from an expert. With eye injuries constituting a significant percentage of all combat casualties, these problems must be rectified. Unfortunately, the technology to do so is not immediately available.

To extend the availability of definitive ophthalmic care into the field medical system, two problems need to be addressed: a field portable digital ophthalmoscope should be developed which is non-mydriatic, has a relatively large field of view, is easy to operate, and is ruggedized to meet military storage and operation standards; high quality digital fundus images should be acquired and transmitted back to home bases where careful inspection of the fundus and accurate assessment of visual function can be performed promptly by eye care specialists. This would allow the provider on the scene to receive diagnostic and treatment recommendations from experts with detailed, immediate knowledge of the case.

Laser Diagnostic Technologies, Inc. is a company specializing in the development of scanning laser-based ophthalmic imaging devices. Our COTS scanning laser ophthalmoscopes are non-mydriatic, compact, easy-to-use, and inherently acquire and store images of the fundus digitally, offering most of the capability requested in the topic. Our goal is to develop a rugged field portable ophthalmoscope/fundus camera based on our existing COTS ophthalmoscopes. We will also develop the software necessary to enable the digital fundus images to be transmitted worldwide via standard modem, implementing a system of 'telemedicine' to extend the availability of specialized ophthalmologic care to the field.

The Phase I program was designed to survey existing ophthalmoscope/fundus camera technology to establish an awareness of the state-of-the-art in this field. We also investigated the nature and frequency of combat related eye injuries and used this information to determine the capabilities of a desired baseline system. The performance envelope of the baseline system has been specified based on the military standards for equipment design and environmental test requirements. A feasibility/design trade-off study has been conducted on the desired capabilities and the performance envelope. Software development has been carried out to successfully demonstrate the feasibility of implementing telemedicine capability into our existing COTS ophthalmoscope. We have also developed a proof-of-concept hardware to show the feasibility of implementing visual acuity testing into our COTS system.

2. Methods and Results

2.1. Survey of existing ophthalmoscope/fundus camera technology.

A survey of existing ophthalmoscope and fundus camera technology was conducted to establish a general awareness of the state-of-the-art in this field. The resources used in the survey included NERAC Inc. (an information service company), publicly available information on the Internet, the Science and Engineering Library and Biomedical Library at the University of California, San Diego, and technical information obtained from ophthalmic equipment

manufacturers. In this survey, current retinal imaging technologies were divided into four categories:

1. ophthalmoscopes (direct and indirect),
2. slitlamp biomicroscopes with handheld retinal imaging lens,
3. fundus cameras,
4. scanning laser ophthalmoscopes.

2.1.1. Ophthalmoscopes (direct and indirect).

The direct or indirect ophthalmoscopes for fundus examination require experienced practitioners. The field of view is usually small, and hardcopy or digital image output is usually not available. Therefore, these types of devices were excluded from further consideration.

2.1.2. Slitlamp Biomicroscopes.

The slitlamp biomicroscopes with a handheld retinal imaging lens are sometimes used to image the retina, and video output of the retinal images is possible. However, reflections from the patient's cornea and the handheld lens are hard to avoid, and fundus image quality is relatively poor. Therefore, this type of device was excluded from further consideration.

2.1.3. Fundus Cameras.

Fundus cameras are today's standard in retinal imaging. The instruments are designed to illuminate the patient's retina with a bright flash of visible light, and the reflected light from the retina is imaged onto a 35 mm photographic film to generate a hardcopy. A CCD camera can be adapted into the systems to generate video image output which can then be digitized. Pupil dilation is usually required. Although there are manufacturers offering non-mydriatic fundus cameras, the field of view is usually smaller and minimum pupil size is about 4 mm. Also, the inherent inefficiency of light collection of these devices require extremely high levels of illumination of the patient's retina. Technical data on all existing COTS non-mydriatic fundus cameras were collected as part of the survey:

Manufacturer	Country of Origin	Model No.	Min. Pupil Size [mm]	Field Size(s) (diagonal)
Canon	Japan	CR5-45NM	3.7- 4	37° (45°)
Kowa	Japan	VX-1	4	45°, 21°
Nidek	Japan	3D-X NM	4	32°
Nikon	Japan	NF-505	3.9	50°, 30°, 20°
Topcon	Japan	TRC-NW5SF	3.5	45°, 20°

2.1.4. Scanning Laser Ophthalmoscopes.

Scanning laser ophthalmoscopes employ a low intensity laser beam scanning across the retina to acquire images. No pupil dilation is required. Figure 1 shows the detection scheme of a scanning laser ophthalmoscope vs. that of a fundus camera: the scanning laser ophthalmoscope employs a point-for-point sequential imaging method. This means that, at any time, the illumination is only applied to a small retinal area (about 10 microns diameter) the laser beam is pointing at. In a parallel illumination system (i.e. fundus camera), <u>all</u> retinal locations are illuminated at the same time, and the light being reflected from <u>all</u> retinal locations has to be simultaneously imaged on photographic film or a CCD camera. Therefore, the total amount of light that has to enter the eye must be about a thousand times larger in a fundus camera than in a scanning laser ophthalmoscope. In order to allow enough light to enter and

exit the eye with a fundus camera system, the pupil size must be relatively large. Even in non-mydriatic fundus cameras, the pupil size has to be about 4 mm which is most often only obtainable after some dark adaptation of the eye to be examined. In a scanning laser instrument, the minimum pupil size is determined by the width of the laser beam entering the eye (typically 1.5- 2.0 mm).

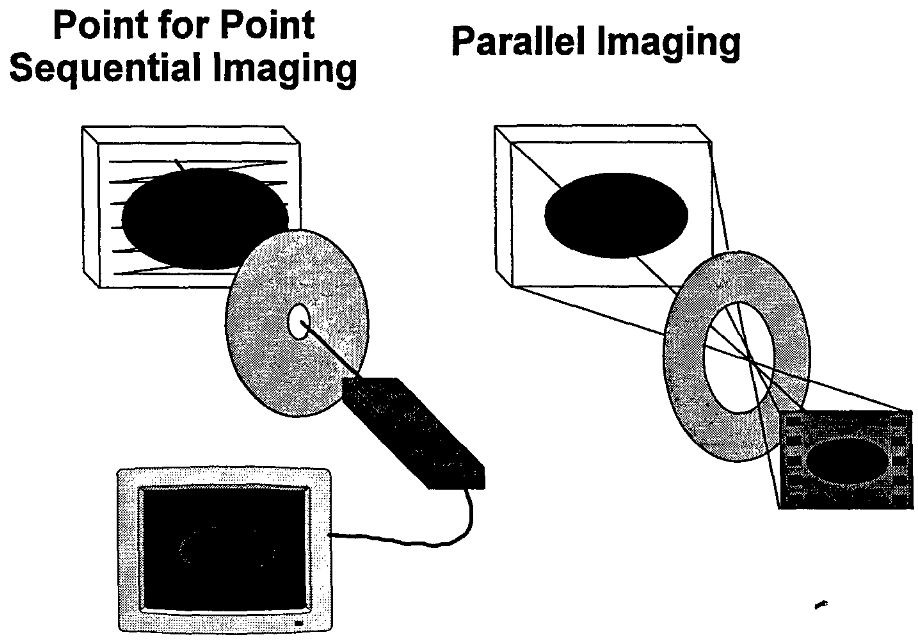


Figure 1: Schematic principles of scanning laser ophthalmoscope (left) and fundus camera (right).

The fast imaging capability of scanning laser ophthalmoscopes permits real-time imaging of the fundus which can be displayed on a video monitor or stored digitally. Four companies are currently offering COTS scanning laser ophthalmoscopes. Technical data on all existing COTS scanning laser ophthalmoscopes were collected as part of the survey. Based on the inherent advantages of the scanning laser technology over conventional fundus imaging techniques, we propose that the baseline system of the field portable digital ophthalmoscope be based on a scanning laser ophthalmoscope.

Manufacturer	Country of Origin	Model No.	Min. Pupil Size [mm]	Field Size(s) (diagonal)
Heidelberg Engineering	Germany	HRA	1.5	42°, 28°, 14°
Laser Diagnostic Tech.	USA	AngioScan	1.5	42°, 28°, 14°
Rodenstock	Germany	SLO-101	1.5	60°, 40°, 20°
Zeiss	Germany	CLSO	1.5	40°, 20°

2.2. Desired capabilities of the ideal system based on the nature and frequency of combat related eye injuries.

The nature and frequency of combat-related eye injuries were investigated. A number of publications have shown a trend toward increasing percentages of ocular injuries in recent wars. While ocular injuries accounted for only 0.57% of casualties in the American Civil War,

the incidence rate increased to an estimated 5% to 9% during the Vietnam conflict and 13% for Operations Desert shield and Desert Storm (1).

The majority of ocular injuries were fragmentation-related. Blast fragmentation from munitions caused 78% of the injuries reported during Operation Desert Storm (2), in which an intraocular foreign body should be suspected (3). A retinal examination would have been appropriate in these situations. Two laser injuries of the macular area were documented in Operation Desert Storm. Although this is a small number, an increasing dependence on laser devices for target acquisition and range finding might result in larger numbers of laser-related eye injuries in the future (2).

We used this information of combat-related eye injuries as a guide to determine the desired capabilities that an ideal system should possess to maximize its effectiveness for the intended application.

For each type of posterior ocular injuries, we defined the necessary requirements for a field portable ophthalmoscope/fundus camera:

2.2.1. Intraocular foreign body

The detection of an intraocular foreign body typically requires a large field and preferably a large focal range which allows the operator to focus through the vitreous and retina.

2.2.2. Retinal damage/vitreous hemorrhage

The appearance and visibility of the retina vary with the cause and amount of bleeding in the vitreous cavity. Because the peak light absorption of hemoglobin is in the green wavelength range, the proposed system should employ a red or near-infrared light source to penetrate blood filled cavities. A large field of view and large focus range is also important.

2.2.3. Hyphemia

Contusive forces frequently tear the iris vessels and damage the anterior chamber angle, which could cause blood in the acqueous and acute glaucoma (4). To perform retinal exams in this situation, a red or near-infrared wavelength light source will be required and a detailed view of the optic nerve head is necessary requiring high magnification fundus images.

2.2.4. Macular laser burn

Large field of view is useful for initial detection. Then a smaller field of view and higher magnification will be helpful in quantifying the damage (i.e. the distance of the laser burn from the fovea).

2.2.5. Other requirements

The proposed digital ophthalmoscope/fundus camera is intended for acquiring a fundus image through the undilated pupil. Although not required of an ophthalmoscope/fundus camera, an ideal field portable ophthalmoscope should also be capable of obtaining digital external ocular images to document the large number of external and anterior eye injuries (corneal/scleral laceration, traumatic cataract, corneal/scleral foreign body etc.).

Visual acuity measurement is usually performed in ocular injury cases. In the field such a test is usually performed using a near-vision card (at a distance of 14 inches) and the patient's corrective lens. However, there are situations when light perception is severely impaired and yet the possibility of visual recovery still exists, e.g., eyes with the presence of intraocular hemorrhage. Therefore, the capability of performing simple visual acuity measurements (even on eyes with intraocular hemorrhages) with the proposed system is highly desirable.

2.3. Performance envelope within which the ideal system should function.

We have investigated the performance envelope within which an ideal system is to be operated and be stored. The proposed system is envisioned for use in a field hospital or in a mobile medical aid station. Therefore, the design of the system should keep in mind the environmental conditions, reliability expectations, transportation, portability, and setup issues, etc. The military standards MIL-STD-210C which provides climatic information to determine design and test requirements and MIL-STD-810E which provides environmental test methods and engineering guidelines, were used as guidelines to determine the performance envelope for the ideal system.

2.3.1. Meteorological variations

Three climate types are defined in MIL-STD-810E based primarily by temperature and secondarily by humidity as hot, basic, cold and severe cold regions. As a field portable system, the ideal digital ophthalmoscope should be able to withstand the meteorological variations covering most climatic regions. We set the initial expected system performance as follows:

Storage temperature:	-40°C ~ +60°C (-40°F ~ +140°F);
Storage relative humidity:	3% ~95% non-condensing;
Operating ambient temperature:	-20°C ~ +49°C (-4°F ~ +120°F);
Operating relative humidity:	5% ~ 60% non-condensing.

2.3.2. Ergonomic concerns

The imaging system will be a table-top unit with the patient sitting up during eye examination.

2.3.3. Reliability expectations

The imaging system is expected to have no performance degradation during its entire life cycle under specified operating and storage conditions, or after experiencing normal handling and transportation.

2.3.4. Transportation and portability

Shock: The imaging system will require a shipping container. The container's cushion design should be based on the typical fragility for medical electronic equipment of 40g peak acceleration. While securely packed into the container, the device should be able to withstand a 30 ~ 36 in. drop test on all facets of the container, in accordance with the shock test described in MIL-STD-810E Method 516.4 Procedures III.

Vibration: The imaging system should be able to withstand transportation/cargo-induced vibration when shipped as secured cargo by land, sea, or air via common carrier, in accordance with MIL-STD-810E Method 514.4.

Rain and water leakage: The container should be water proof to prevent damage during handling or transportation in a rainy weather or high humidity region.

Sand and dust: The container should be tight to prevent sand or dust invasion during transportation. The housing of the imaging system should also be designed to prevent the penetration of the dust particles into the system while the system is taken out of its container.

Portability: Our current COTS scanning laser ophthalmoscope's scan head weighs about 10.5 Kilograms and has a dimension of 17 x 12.75 x 12.5 inches. Its packaged dimensions are 21 x 18 x 18 inches. The proposed system should weigh no more than the existing unit and its package should fit into a protective container acceptable under military standard.

2.3.5. Setup and Compatibility

An existing rugged field portable personal computer (IBM-compatible, preferably with Pentium 100 MHz processor) will be used with the proposed imaging system. The computer should have at least one ISA bus slot on its motherboard and enough clearance for mounting electronic circuit boards.

Multiple power plants or power generators are usually available in a field hospital. The power types are 115-120 VAC and 220-240 VAC, with 100 kW breakdown limit. The proposed imaging system will support both types of primary circuits: 115-120 VAC (50-60 Hz) and 220-240 VAC (50-60 Hz).

2.4. Feasibility/design trade-off study on the proposed system based on the desired capability and defined performance envelope of the ideal system.

The proposed system is envisioned for use in a field hospital or in a mobile medical aid station. In general, the imaging device should be simple to operate and user friendly so minimally trained personnel can operate the device and obtain meaningful images to take advantage of the system's telemedicine capability. A large field of view is desired without the need for pupil dilation. Multi-functionality of the system is preferred without compromising the system's simplicity so that not only posterior eye injuries can be diagnosed but also the external and anterior segment injuries can be documented. System design and packaging should be based on the defined performance envelope.

2.4.1. Design/trade off study of the desired capabilities

The capabilities desired of the proposed system and potential or actual trade-offs are listed in Table 1.

2.4.1.1. Resolution

The optical resolution of a fundus camera/ophthalmoscope is limited by the optical properties of the patient's eye to about 11 microns. Ideally, the digital resolution should match the optical resolution. At a field of view of 50°, the digital resolution would need to be about 1200 by 1200 pixels to match the optical resolution. For the proposed application, the 50° images are for orientation and the detection of larger foreign bodies only. Most likely, a digital resolution of 512 by 512 or even 256 by 256 pixels would suffice for this application. We plan to implement a zoom-function which allows the observer to focus onto a smaller field of view of about 15° to obtain highest resolution, high magnification images. Preliminary clinical studies in Phase II will show which resolution represents the best compromise between speed of transmission and resolution of clinically significant details.

2.4.1.2. Field of view

The detection of an intraocular foreign body and retinal detachment typically requires a large field of view. A field of view of 50° or even 60° would be desirable in some cases. Through the undilated pupil, a 50° field of view is possible without compromising other requirements, i.e. working distance from the patient's eye.

2.4.1.3. Wavelength of illumination source

The realization of full-color imaging with scanning laser technology is technically feasible, but would result in a complex three-laser system (red, blue, green). Current options for laser sources in the blue wavelength are restricted to Argon-Ion gas lasers which are not

Table 1: The ideal design and trade-offs of the proposed field portable fundus camera/ ophthalmoscope.

	Ideal Design	Trade-offs	Phase II System
Pupil Dilation	Non-mydriatic	none, design requirement	laser beam width ≤ 2.0mm
Resolution (Optical)	11 µm	none	11 µm
Optical principle	scanning laser	true color imaging would require three lasers (too complex for field use)	single scanning laser
Image Resolution (Digital)	11 µm/pixel	max. resolution images would be 1200 by 1200 pixels, resulting in slow image acquisition and tele-transmission. 256 pixel by 256 pixel or 512 by 512 are good compromises between speed and resolution.	11 µm/pixel for 15° field (diagonal). 256 by 256 pixels. Field size variable. (512 by 512 pixel resolution requires electronics redesign)
Field of View	50° (diagonal)	none	50° (diagonal), modification of optics
Wavelength of Illumination Source	3-color and infra-red	color images would require complex, alignment critical three-laser system. Gray tone images acquired in near-infrared give similar results as "red-free" fundus images.	Gray tone images acquired in near-infrared, no change to system. Implement second laser (visible) for visual acuity testing.
Focusing Range (posterior chamber)	± 6mm	none	modification to optical system
Exterior Ocular Imaging Capability	yes	none	implement additional optics and electronics
Anterior Chamber Imaging Capability	yes	none	implement additional optics and electronics
Visual Acuity Testing Capability	yes	none	implement second laser, software and electronic hardware.
Field -portable	compact, tabletop equipment	none; however hand-held device would be hard to use by untrained users.	mechanical redesign
Capture Digital Fundus Image	yes	speed of acquisition and data transmission is dependent on digital resolution.	redesign for 512 by 512 pixel resolution, if needed
Live Image Display	yes	none	no additional work
Telemedicine Capability	yes	none, design requirement	continue software development effort
Software for Trans-mitting Images	yes	none, design requirement	continue software development effort

reliable, small, and stable enough for the planned application. Future availability of diode lasers emitting blue wavelength light of sufficient power would make full color laser imaging more practical. For the proposed system, we are suggesting the use of a near-infrared laser light source of 780 nm wavelength, resulting in a monochromatic fundus image similar to the "red-free" images acquired with a fundus camera. An additional advantage of a laser beam of this wavelength is that it can penetrate the intraocular media even in the presence of hemorrhage.

2.4.1.4. Focusing Range

The focusing range of the current COTS scanning laser ophthalmoscope is ±3 mm. A larger focal range through the vitreous and retina will be helpful in cases of locating intraocular foreign bodies. To increase the focusing range to the desired ±6mm, we need to modify the internal focusing optics. We can also consider reducing the imaging beam width which will increase the depth of focus, but then we will be compromising the optical resolution of the system.

2.4.1.5. Exterior ocular imaging and anterior segment imaging capabilities

The capabilities of obtaining digital exterior ocular images and of obtaining digital anterior chamber images are valuable features for the proposed system to have. Additional optical components need to be added to the current COTS ophthalmoscope to change the imaging optics. Mounting of the additional optical components should be in a way so that they can be inserted or removed easily from the scanning laser beam path to serve the purposes of exterior ocular imaging, anterior chamber imaging, or fundus imaging, respectively. An alternative is the integration of a CCD camera for the purpose of exterior ocular imaging while the scanning laser would be employed for fundus imaging. If this alternative method is to be used, software and electronic hardware modifications will be necessary to meet the need of multi-channel imaging. A feasibility study to be carried out during the Interim SBIR Phase of this project will show which of the two alternatives will be more appropriate for the desired system.

2.4.1.6. Visual acuity testing capability

A simple visual acuity measurement device can be implemented into the field portable digital ophthalmoscope. We will integrate a visible diode laser light source into the current COTS system. The visible laser beam is co-axially aligned to the near infrared imaging laser beam and it can be rapidly modulated through a control software. During the visual acuity test, the visible laser is turned on only for two scan lines which are projected onto the patient's retina. The distance between the two scan lines can be varied through the control software. The visual acuity can then be determined based on the minimum distance between the two scan lines which the patient can resolve. Proof-of-concept hardware development was successfully carried out in Phase I (see detailed description in paragraph 2.6).

2.4.1.7. Telemedicine capability

One of the requirements of the proposed system is to have telemedicine capability. The operator in the field should be able to acquire a high quality digital image by simply pushing an image acquisition button. The image will then be transmitted through the Internet to a remote station. A specialist at the station can view the image and send feedback messages to the operator in the field. To perform this task, the computer of the imaging system and the one of the remote station will both be equipped with modems and be connected via standard telephone, ISDN or ATM lines to Internet providers. In Phase I, we successfully demonstrated the feasibility of acquiring digital fundus images with our COTS scanning laser ophthalmoscope and transmitting these over the Internet through 28.8 kB/s modems and standard phone lines (see detailed description in paragraph 2.5).

In order to conduct real-time video teleconferencing with the proposed system, both real time image acquisition and real time image transmission need to be achieved. While the current COTS scanning laser ophthalmoscope can already acquire and display real time fundus images, we will need to develop software for real-time video image transmission. Suitable high speed networking services are needed to test real time image transmission (5). Switch-based wide area networking services such as ISDN or ATM will be appropriate. The bandwidth range of ISDN is from 64 Kb/s (basic rate interface, BRI) to 1.92 Mb/s (primary rate interface, PRI), while ATM can support from 1.54 Mb/s (T1) to 2.4 Gb/s (OC-48) and beyond.

We will also consider reducing the amount of data to be transmitted in real time. For example, we can acquire and transmit real-time images of lesser resolution (128 by 128 pixels) which would be sufficient for identifying landmarks and/or areas of interest on the fundus. Based on the feedback instructions from the remote viewing station, individual images of higher resolution (256 by 256 pixels or higher) could then be captured and transmitted for a more detailed view of the area of interest. A feasibility study of transmitting real-time fundus images will be carried out during the interim SBIR Phase of this project.

2.4.2. Design/trade off study of the desired performance envelope

The current COTS scanning laser ophthalmoscope is designed to satisfy commercial environmental requirements. The desired performance envelope of the proposed system and the performance envelope of the current COTS system are given in Table 2.

2.4.2.1. Meteorological variations

Based on the temperature range defined in Table 2, an ideal system should be operational in the hottest area of the world where high temperatures of 49°C (120°F) occur at the frequency of 1% as well as in a severely cold region such as Siberia where low temperatures of -51°C (-60°F) occur at the frequency of 20%.

The current COTS system is designed to meet the operating range of a commercial instrument. While the humidity range defined in Table 2 is not too difficult to meet, the operational low temperature range will certainly pose a challenge. Besides improving the operating range of each component, the implementation of an internal temperature control device to warm or cool the scan electronics and laser pre-operationally might be necessary.

2.4.2.2. Packaging design and system mechanical design

The packaging of the scan head of the proposed system will be redesigned to meet military standard for shock hardening, vibration isolation, rain and water leakage, sand and dust damage as described in MIL-STD-810E. The system should be handled and transported as secured cargo in its container. The cushion design of the container should meet the requirement of medical electronic equipment of 40g peak acceleration. Polyurethane can be a good candidate for cushion material since it is an effective absorber and can withstand extremes of temperature from -50°F up to 250° F with very little change. While securely packed into the container, the device is expected to withstand 30 ~ 36 in. drop test on all facets of the container. The container design should also be water proof and sand and dust proof to prevent damage to the device.

Mechanical design of the current COTS system should be carefully inspected to be certain that transportation/cargo-induced vibration will not cause loose fasteners, optical misalignment, component fatigue, or cracking and rupturing, etc. The housing of the current COTS scanning laser ophthalmoscope consists of three pieces of polypropylene. A more protective and rugged design will be considered.

Table 2: The desired performance envelope of an ideal system and the performance envelope of the current COTS scanning laser ophthalmoscope.

	Ideal Design	Current COTS System	Phase II System
Ambient Temperature	Storage: -40°C ~ +60°C (-40°F ~ +140°F); Operating:-20°C ~ +49°C (-4°F ~ +120°F);	Storage: -20°C ~ +60°C (-4°F ~ +140°F); Operating:+18°C ~ +24°C (+64°F ~ +75°F);	Storage: -20°C ~ +60°C (-4°F ~ +140°F); Operating: 0°C ~ +40°C (+32°F ~ +104°F);
Relative Humidity	Storage: 3% ~ 95% noncondensing; Operating:5% ~ 60% noncondensing;	Storage: 15% ~ 95% noncondensing; Operating:20% ~ 60% noncondensing;	Storage: 3% ~ 95% noncondensing; Operating:5% ~ 60% noncondensing;
Shock (non-operational)	40g peak acceleration	commercial equipment grade	40g peak acceleration
Vibration	transportation/cargo-induced vibration as secured cargo	commercial equipment grade	transportation/cargo-induced vibration as secured cargo
Rain and Water leakage	water proof packaging	no requirement	water proof packaging
Sand and Dust	sand and dust proof housing and packaging	no requirement	sand and dust proof housing and packaging
Altitude (operational)	-1000 to +12,000 feet (-304 to 3048 meters)	commercial equipment grade	-1000 to +12,000 feet (-304 to 3048 meters)
Dimensions (Scan Head)	compact	17 in. x 12.8 in. x 12.5 in.	17 in. x 12.8 in. x 12.5 in. or smaller
Dimensions (Scan Head, Packaged)	compact	21 in. x 18 in. x 18 in.	min. 21 in. x 18 in. x 18 in.
Weight (Scan Head)	≤ 15 kilograms	10.5 kilograms	15 kilograms or less
Packaging	military standard protective container	commercial equipment grade	military standard protective container
Transportation	land, sea, or air via common carrier as secured cargo	land, sea, or air via common carrier as secured cargo	No change
Computer System	military standard rugged computer system	commercial computer system	military standard rugged computer system
Electrical Power Supply	115-120 VAC (50-60 Hz) and 220-240 VAC (50-60Hz)	115-120 VAC (50-60 Hz) and 220-240 VAC (50-60Hz)	No change
Ergonomic Concerns	table-top equipment	workstation set-up	table-top equipment

Both the system and container design should be compact and light weight to ensure field portability. The system and its cushion should fit into a protective container which meets military standard size.

2.4.2.3. Ergonomic concerns

The proposed system will be a table-top unit with the patient sitting up during eye examination, which is similar to the set up of the current COTS scanning laser ophthalmoscope. A redesign of the housing of the system will be necessary to comply with the extended performance and environmental requirements. Based on cost effectiveness, we will not further consider the alternative of imaging a lying down patient.

2.4.2.4. Computer system

The commercial computer system of the current COTS scanning laser ophthalmoscope will be replaced by a military grade IBM-compatible computer system. Datametrics Corporation (DMC) has been the leading supplier of rugged computer systems and peripheral equipment. Its rugged portable workstation is designed and constructed for rugged military environment, and features Pentium processor, 84 key sealed keyboard, removable hard drive, SVGA video port, and Ethernet Lan. In addition, one ISA bus slot on the mother board and enough space to mount our frame grabber board and scanner control board is needed.

2.4.2.5. Electrical power supply

The current COTS system can already support both types of primary circuits: 115-120 VAC (50-60 Hz) and 220-240 VAC (50-60 Hz). No modification is necessary.

2.5. Software development to acquire, store, and transmit digital fundus images and demonstration of telemedicine feasibility.

A software program has been designed and written to capture, transmit and display digital fundus images across both a local area network and the Internet. Connections to the Internet were established through a local service provider using two US Robotics 28.8 kbps modems and two separate phone lines.

The program has been written in Borland C++ Builder, with some Assembler code, runs under the Windows 95 operating system, and can be easily modified to run under the Windows NT operating system. The software is ODBC (open database connectivity) and Y2K (year 2000 problem) compliant to meet the Department of Defense Automated Information System Requirements.

Figure 2 is a photograph of the set-up for demonstrating telemedicine feasibility. Two Pentium 100 MHz computers were used: one for the imaging device (on the right), and the other as a remote viewing station (on the left). The imaging device was one of our existing COTS scanning laser ophthalmoscope (in the middle). Figure 3 shows the control panel of the software. Once "Live Mode" was selected, live images of the fundus were displayed on the LCD screen of the scanhead as shown in the center of Figure 2. The operator pressed the "Capture Fundus Image" button on the screen (Figure 3) to capture a single frame image, which then was displayed on the computer monitor of the imaging device (Figure 2 right side and Figure 3). Whenever a fundus image was captured, it was immediately stored in the instrument's database. By selecting the "XMT Record" button (Figure 3), the operator could transmit an image via modem and Internet to the viewing station. Once the remote viewing station received the image, the image was displayed on its computer monitor and stored in its local database

(left side of Figure 2). For both the imaging device and the remote viewing station, a "Zoom Image" function is available (Figure 4).

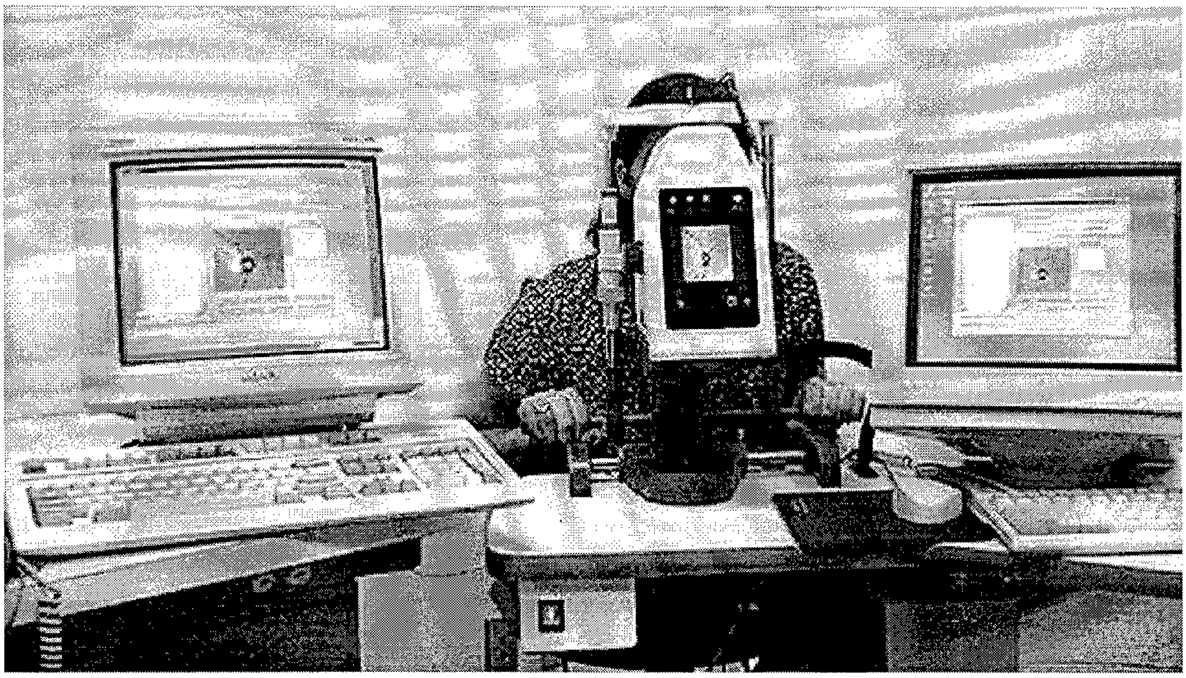


Figure 2. Set-up for telemedicine feasibility test. On the right is the computer monitor for the imaging device, in the center is one of our COTS scanning laser ophthalmoscopes, and on the left is the computer monitor of the remote viewing station.

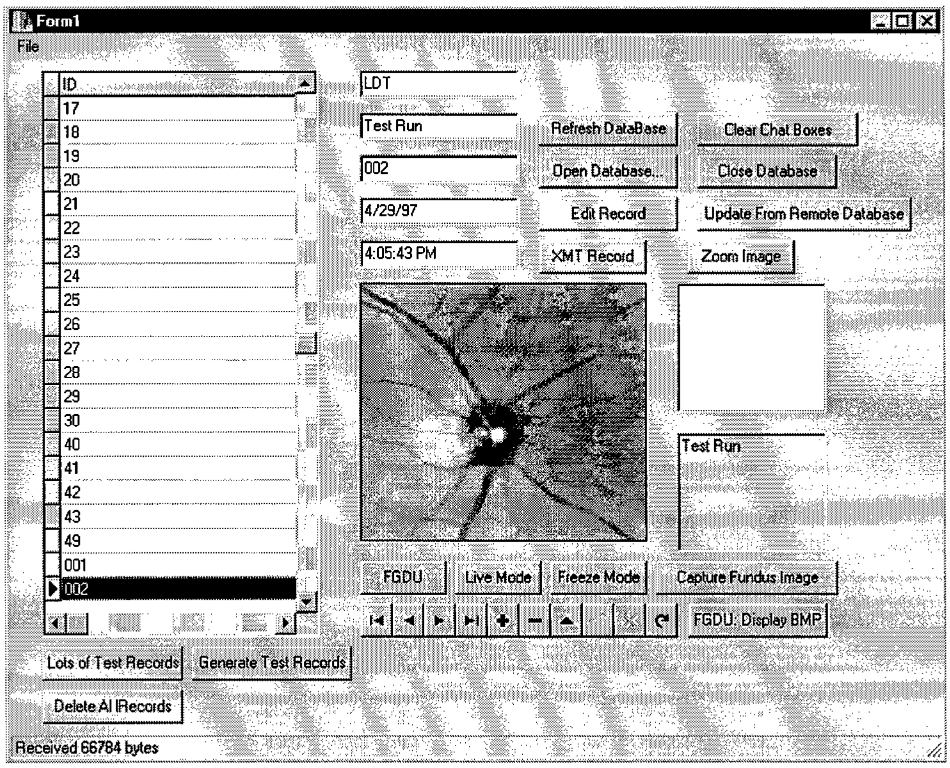


Figure 3. Screen capture of the monitor of the imaging device showing the control buttons of the software and a captured fundus image.

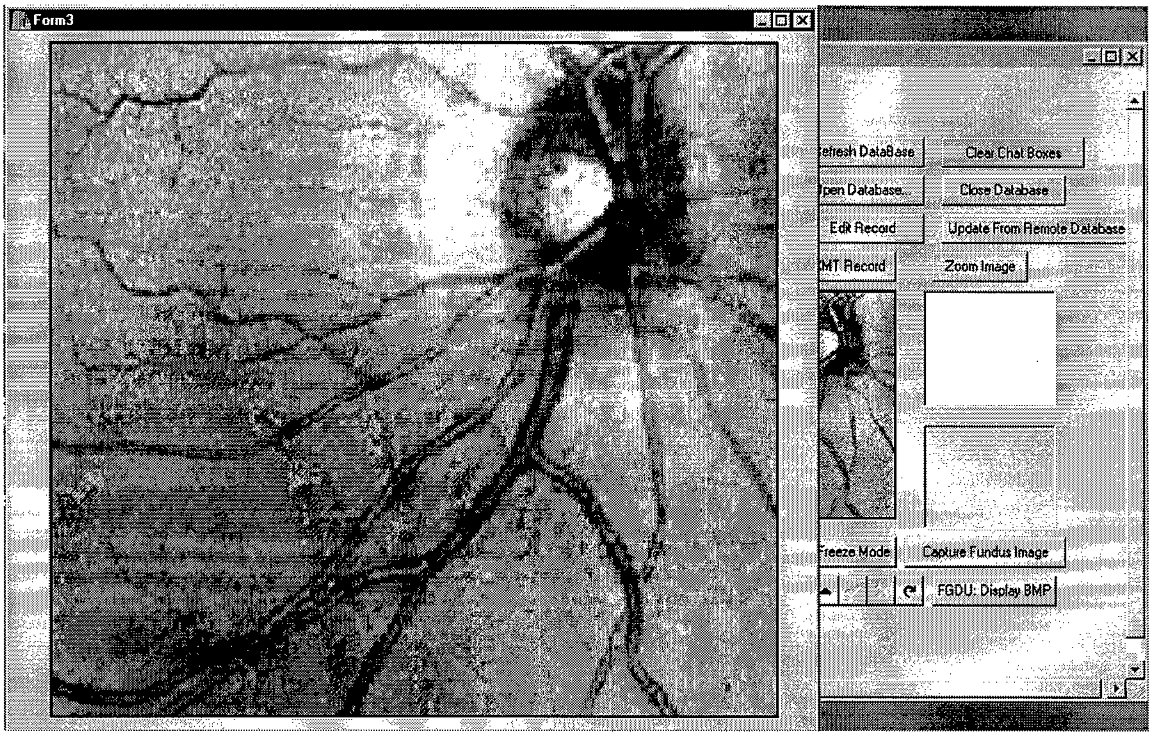


Figure 4. Screen capture of the monitor of the remote viewing station showing a transmitted fundus image and the "Zoom Image" function of the software.

In order to study the ability of the software to work in a peer-to-peer multi-user database situation, a second test was performed. The imaging device and the remote viewing station were connected via an Ethernet 10BaseT local LAN. Identical databases of captured images were opened at the same time at both the imaging device and the remote viewing station. Then, changes were made to the database on the imaging device's computer. Subsequently, the operator of the remote viewing station clicked on the button "Refresh Database", and the database on the viewing station was automatically updated to the modified database of the imaging device

To measure the image transmission speed both across the local area network and the Internet (through 28.8 kbps modems), we transmitted 100 digital fundus images. In the case of the local area network connection (10BaseT) which runs at a maximum speed of 10 Mbps, the average time for transmitting a digital image of 66,784 bytes size (one frame) was 0.363 seconds. In the case of transmitting the images through the Internet with 28.8 kbps modem, the average time to transmit one image frame was 22.6 seconds.

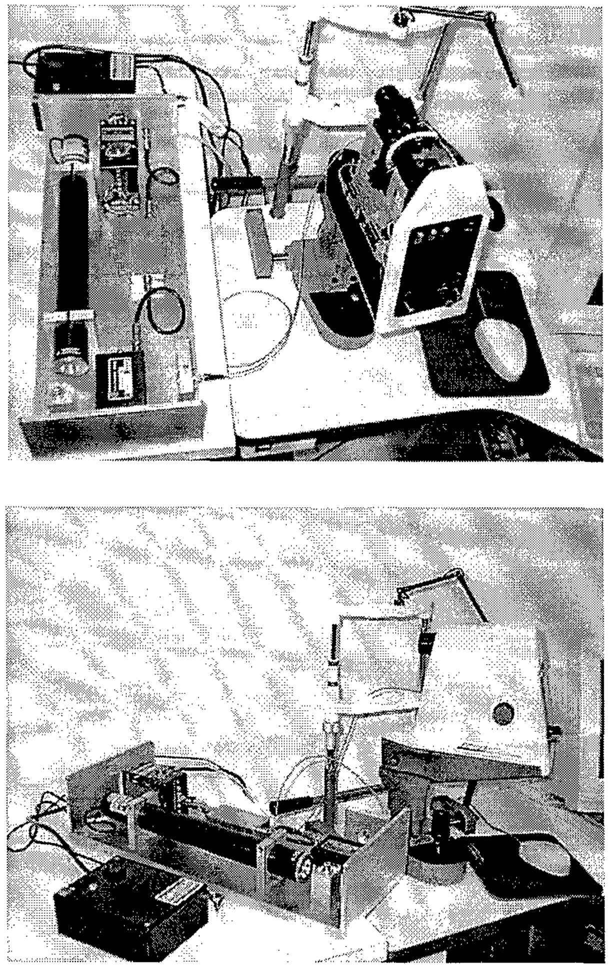
2.6. Proof-of-concept hardware to address feasibility of performing visual acuity measurement with the proposed system.

To perform visual acuity measurement, we modified one of our COTS scanning laser ophthalmoscopes by coupling a visible light source to the instrument via a fiber optic cable. Figure 5 shows the set-up viewed from two different angles. The visible light source consisted of a HeNe laser (wavelength 633 nm), an acousto-optic light modulator, and the fiber-optic

delivery system. By driving the acousto-optic light modulator via software and a Digital-to-Analog converter, the intensity of the HeNe laser beam could be varied in 256 steps from 0 to about 300 μW. The visible HeNe laser light was coupled co-axially with the near-infrared laser beam of our COTS scanning laser ophthalmoscope. We could obtain live digital fundus images from the near infrared laser which could be hardly perceived by the patient. The modulated HeNe beam, however, was perceived as a highly visible pattern on the retina.

We developed an electronic circuit that allowed us to address the acousto-optic modulator in synch with the scanning mechanism of the COTS scanning laser ophthalmoscope. Using a synchronized modulation of the HeNe laser, we could show the projection of various, pre-programmed patterns onto the patient's retina. For this feasibility study, we programmed targets consisting of either a single dot with programmable location, a checker-board pattern, or a line. Examples of pre-programmed patterns are shown in Figure 6. With additional software development, more complicated patterns can be programmed.

While we used a HeNe laser and acousto-optical modulator for this feasibility study, a simple visual acuity measurement as proposed might only require a visible diode laser as a light source, which remains to be tested during Phase II of this project.



A

B

Figure 5. Set-up for the feasibility study of performing visual acuity measurement. On the left is the fiber-coupled He-Ne laser source with acousto-optic light modulator. On the right is the modified COTS scanning laser ophthalmoscope. **A**: Viewed from top with scanhead cover off. **B:** Viewed from left with scanhead cover on.

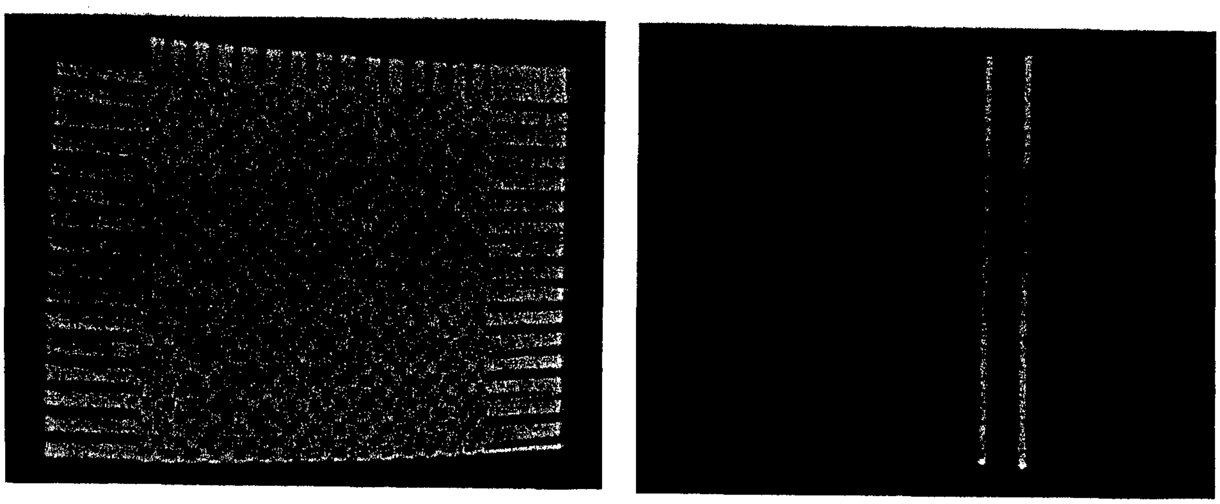


Figure 6. Examples of pre-programmed patterns projected onto a flat screen simulating a patient's retina (Distortion seen in the patterns is due to the viewing angle of photographing).

3. Conclusions

With eye injuries constituting a significant percentage of all combat casualties, the need of providing proper, definitive ophthalmic care in the field medical system is obvious. A rugged field portable digital ophthalmoscope/fundus camera with telemedicine capability needs to be developed to serve this purpose. In general, the system to be developed will be non-mydriatic, compact, and easy to operate. An ideal system will be able to serve multiple purposes besides fundus imaging, such as external ocular imaging and visual acuity testing, etc. Large field of view and large focusing range are also desirable. To be suitable for telemedicine, images acquired should be in digital format and of good quality so that they can be transmitted through networking services to a remote viewing station in order to get experts' opinion.

During Phase I, we have surveyed the existing ophthalmoscope/fundus camera technology to establish an awareness of the state-of-the-art in this field. Based on the survey results, we consider the scanning laser ophthalmoscope as the most suitable technology currently available as a base for the proposed system. We also investigated the nature and frequency of combat related eye injuries and used this information to determine the capabilities of a desired baseline system. The performance envelope of the baseline system has been specified based on the military standards for equipment design and environmental test requirements. A feasibility/design trade-off study has been conducted based on the desired capabilities and the performance envelope. Software has been developed to acquire, store, and transmit digital fundus images, and we have been able to successfully demonstrate telemedicine feasibility with our existing COTS scanning laser ophthalmoscope. Hardware for implementing basic visual acuity testing into the existing COTS scanning laser ophthalmoscope has been developed and successfully tested. We were able to project pre-programmed patterns at visible wavelength onto the retina while at the same time the near-infrared scanning laser provided a live image of the fundus.

For commercial applications, a field portable ophthalmoscope could allow the diagnosis of ocular trauma and disease to become more readily available, even outside of clinics and hospitals, increasing the possibility of early diagnosis and raising the standard of care. The added capability of telemedicine, linked through the vast reach of the Internet, offers a practicable way of bringing specialized ophthalmologic care to more patients over any distance and at any time, at the equivalent cost and convenience of sending E-mail.

4. References

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5. List of Personnel

The following personnel participated in this Phase I project:

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Laser Diagnostic Technologies, Inc.

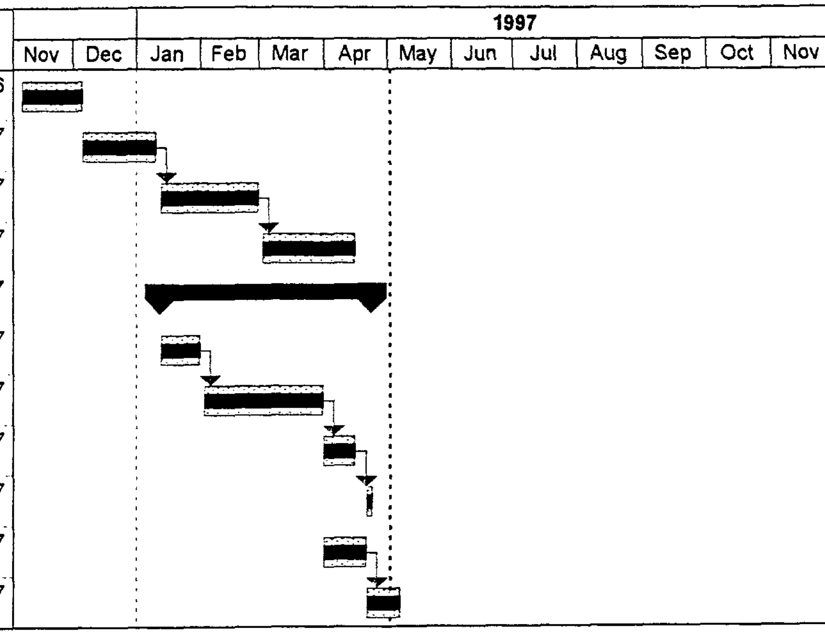
Frank Scavo
Director, New Product Development
(no longer with Laser Diagnostic Technologies, Inc.)

6. GANTT chart

A GANTT chart of the complete Phase I project is printed on the following page.

FIELD PORTABLE DIGITAL OPHTHALMOSCOPE/FUNDUS CAMERA

ID	Task Name	Duration	Start	Finish
1	SURVEY OF EXISTING TECHNOLOGY	22d	11/6/96	12/5/96
2	DETERMINE DESIRED SYSTEM CAPABILITES	26d	12/6/96	1/10/97
3	DETERMINE PERFORMANCE ENVELOPE	35d	1/13/97	2/28/97
4	DESIGN/TRADE OFF STUDY	32d	3/3/97	4/15/97
5	**SOFTWARE DEVELOPMENT**	**73d**	**1/13/97**	**4/23/97**
6	CONCEPT DESIGN	15d	1/13/97	1/31/97
7	CODING	41d	2/3/97	3/31/97
8	TESTING & DEBUGGING	11d	4/1/97	4/15/97
9	TELEMEDICINE TRIAL	3d	4/21/97	4/23/97
10	DETERMINE PHASE 2 OBJECTIVES	14d	4/1/97	4/20/97
11	GENERATE FINAL REPORT	12d	4/21/97	5/6/97



Project: PORT. OPHTHALMOSCOPE
Date: 5/2/97

Task
Progress
Milestone
Summary
Rolled Up Task
Rolled Up Milestone
Rolled Up Progress

LASER DIAGNOSTIC TECHNOLOGIES INC.

DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
504 SCOTT STREET
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REPLY TO
ATTENTION OF:

MCMR-RMI-S (70-1y) 4 Dec 02

MEMORANDUM FOR Administrator, Defense Technical Information Center (DTIC-OCA), 8725 John J. Kingman Road, Fort Belvoir, VA 22060-6218

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1. The U.S. Army Medical Research and Materiel Command has reexamined the need for the limitation assigned to technical reports written for this Command. Request the limited distribution statement for the enclosed accession numbers be changed to "Approved for public release; distribution unlimited." These reports should be released to the National Technical Information Service.

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FOR THE COMMANDER:

Phyllis Rinehart

Encl

PHYLIS M. RINEHART
Deputy Chief of Staff for
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